IN THE UNITED STATES DISTRICT COURT

FOR THE EASTERN DISTRICT OF VIRGINIA

Richmond Division

JANIE MILLS DODSON,
Plaintiff,

v. Civil No. 3:20cv596 (DJN)

C.R. BARD, INC.,
Defendant.

MEMORANDUM OPINION

Plaintiff Janie Mills Dodson ("Plaintiff") brings this state law products liability action against Defendant C.R. Bard, Inc., now Beckton, Dickinson and Company ("Defendant"), alleging that Defendant negligently designed and manufactured a medical device known as the Bard Simon Nitinol Vena Cava Filter ("SNF"), thereby resulting in permanent injuries to Plaintiff. Plaintiff also alleges that Defendant failed to warn consumers, medical providers and government authorities about the potential injuries caused by the SNF, thereby resulting in the implantation of an unreasonably dangerous device in Plaintiff and causing injuries from which she will not recover. This matter now comes before the Court on Defendant's Motion to Dismiss (ECF No. 16). For the reasons set forth below, the Court hereby GRANTS IN PART and DENIES IN PART Defendant's Motion to Dismiss (ECF No. 16). Specifically, the Court DISMISSES WITHOUT PREJUDICE Counts One and Two of Plaintiff's Amended Complaint (ECF No. 9), but DENIES Defendant's Motion as to Count Three.

I. BACKGROUND

In deciding a motion to dismiss pursuant to Rule 12(b)(6), the Court must accept as true the well-plead factual allegations set forth in Plaintiff's Amended Complaint ("Am. Compl."

(ECF No. 9)). *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). Against that backdrop, the Court accepts the following facts as alleged for purposes of resolving the instant motion.

A. Factual Background

In the early 2000's, Plaintiff underwent a medical procedure that involved the implantation of a permanent filter known as the SNF into her inferior vena cava ("IVC") to prevent blood clots from moving throughout her body. (Am. Compl. ¶¶ 6, 28.) The structure of the SNF includes a small, umbrella-shaped body and six legs, or struts, that extend down from the body. (Am. Compl. ¶ 7.) At the time of implantation, Plaintiff received no warnings from her doctor about potential issues with the device. (Am. Compl. ¶ 29.)

On July 9, 2018, Plaintiff entered a Spotsylvania County hospital for treatment for sepsis. (Am. Compl. ¶ 31.) A CT scan and X-ray revealed that the SNF had become dislodged and tilted within Plaintiff's IVC. (Am. Compl. ¶¶ 31-34.) Five of the SNF's legs had perforated the IVC and another muscle in her body. (Am. Compl. ¶ 34.) Plaintiff underwent surgery on July 12, 2020, in an attempt to remove the SNF. (Am. Compl. ¶ 35.) Doctors retrieved one of the legs of the SNF that had detached from the body of the device, but they determined that retrieving the device itself and the remaining legs appeared too risky. (Am. Compl. ¶¶ 35-36.) Doctors informed Plaintiff that a high likelihood existed that another leg of the SNF would eventually break off and cause further damage, even death, to Plaintiff. (Am. Compl. ¶ 37.) Plaintiff continues to suffer physical and emotional pain due to the issues with the SNF and her anticipation of future problems arising from its permanent placement in her body. (Am. Compl. ¶¶ 42-44.)

On July 6, 2020, Plaintiff filed a Complaint in the Circuit Court for the County of Spotsylvania. (ECF No. 1-1.) On August 4, 2020, Defendant removed the case to this Court on

the basis of diversity jurisdiction. (ECF No. 1.) Defendant filed an initial Motion to Dismiss on August 6, 2020, and, in response, Plaintiff filed an Amended Complaint on August 31, 2020. (ECF Nos. 4, 9.)

B. Plaintiff's Amended Complaint

Plaintiff's Amended Complaint raises three counts for relief based on the above allegations. In Count One, Plaintiff alleges that Defendant acted negligently in the manufacture of the SNF. (Am. Compl. ¶ 45.) Specifically, Plaintiff states that Defendant failed to conduct adequate testing "in animals, or in humans, to determine the manufacturing issues" in the product, and that Defendant "knew or should have known that the lack of testing and/or manufacturing of the SNF would have contributed to the structural failure causing the fracture" of the device. (Am. Compl. ¶¶ 46-47.) In Count Two, Plaintiff alleges that Defendant acted negligently in the design of the SNF, reiterating the same allegations averred in support of Count One, including that Defendant did not conduct adequate testing, and that if it had, Defendant would have discovered the design issues with the device. (Am. Compl. ¶¶ 51-52.) Finally, in Count Three, Plaintiff alleges that Defendant failed to warn consumers, medical providers and government authorities about the injuries caused by the SNF and the high rates of fracture that occurred during the lifetime of the device. (Am. Compl. ¶¶ 57-59.) Throughout her Amended Complaint, Plaintiff cites to several facts, including the results of three studies, FDA complaints and warnings, and Defendant's own marketing materials to support her assertion that Defendant had knowledge of the dangers of the SNF, and thus a duty to warn of the high risks presented by its implantation. (Am. Compl. ¶¶ 9-15, 18-21.) Based on these claims, Plaintiff seeks compensatory and punitive damages from Defendant in the amount of $500,000. (Am. Compl. at 11.)

C. Defendant's Motion to Dismiss

In response to Plaintiff's Amended Complaint, on September 29, 2020, Defendant filed a Motion to Dismiss (ECF No. 16), moving to dismiss Plaintiff's claims for failure to state a claim under Rule 12(b)(6). In support of its Motion, Defendant argues that Plaintiff fails to plausibly allege that any defect, either manufacturing or design, existed in Defendant's product, giving rise to a right to relief. (Mem. in Supp. of Mot. to Dismiss of C.R. Bard ("Def.'s Mem.") (ECF No. 17) at 1.) Rather, Plaintiff's Amended Complaint constitutes "nothing more than a threadbare recitation of the elements of negligent manufacturing, negligent design and failure to warn." (Def.'s Mem. at 1.) Further, Defendant argues that Plaintiff fails to allege a plausible failure to warn. (Def.'s Mem. at 7.) Specifically, Defendant states that no facts in the Amended Complaint suggest that Defendant knew of the alleged defects at the time of implantation, and that Virginia has yet to recognize a post-sale duty to warn. (Def.'s Mem. at 7.) Finally, Defendant argues that Plaintiff's failure to specify the date or year of the SNF's implantation negates all of her claims, because Defendant did not "acquire the rights in and liabilities attributable to the SNF until October 19, 2001." (Def.'s Mem. at 9.)

Plaintiff filed her Memorandum in Opposition to Defendant's Motion to Dismiss on October 13, 2020, (Pl.'s Mem in Opp. to Def. C.R. Bard's Mot. to Dismiss ("Pl.'s Resp.") (ECF No. 19)), and Defendant filed its Reply on October 19, 2020, (Reply Mem. in Supp. of Mot. to Dismiss of C.R. Bard ("Def.'s Reply") (ECF No. 20)), rendering Defendant's Motion now ripe for review.

II. STANDARD OF REVIEW

A motion to dismiss pursuant to Rule 12(b)(6) tests the sufficiency of a complaint or counterclaim; it does not serve as the means by which a court will resolve contests surrounding

the facts, determine the merits of a claim or address potential defenses. *Republican Party of N.C. v. Martin*, 980 F.2d 943, 952 (4th Cir. 1992). In considering a motion to dismiss, the Court will accept a plaintiff's well-pleaded allegations as true and view the facts in a light most favorable to the plaintiff. *Mylan Labs., Inc. v. Matkari*, 7 F.3d 1130, 1134 (4th Cir. 1993). However, "the tenet that a court must accept as true all of the allegations contained in a complaint is inapplicable to legal conclusions." *Iqbal*, 556 U.S. at 678.

Under the Federal Rules of Civil Procedure, a complaint or counterclaim must state facts sufficient to "'give the defendant fair notice of what the . . . claim is and the grounds upon which it rests[.]'" *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007) (quoting *Conley v. Gibson*, 355 U.S. 41, 47 (1957)). As the Supreme Court opined in *Twombly*, a complaint or counterclaim must state "more than labels and conclusions" or a "formulaic recitation of the elements of a cause of action," though the law does not require "detailed factual allegations." *Id.* (citations omitted). Ultimately, the "[f]actual allegations must be enough to raise a right to relief above the speculative level," rendering the right "plausible on its face" rather than merely "conceivable." *Id.* at 555, 570. Thus, a complaint or counterclaim must assert facts that are more than "merely consistent with" the other party's liability. *Id.* at 557. And the facts alleged must be sufficient to "state all the elements of [any] claim[s]." *Bass v. E.I. Dupont de Nemours & Co.*, 324 F.3d 761, 765 (4th Cir. 2003) (citing *Dickson v. Microsoft Corp.*, 309 F.3d 193, 213 (4th Cir. 2002) and *Iodice v. United States*, 289 F.3d 270, 281 (4th Cir. 2002)).

III. ANALYSIS

Assuming that Virginia law applies to Plaintiff's claims, as both parties do in their briefs[1], Plaintiff fails to state a claim upon which relief can be granted as to Counts One and Two of her Amended Complaint. However, her allegations, taken as true and viewed in a light most favorable to Plaintiff, support a plausible right to relief as to Count Three.

To recover under a products liability claim of negligence in Virginia, Plaintiff must show that "(1) the [product] was unreasonably dangerous for the use to which it would ordinarily be put or for some other reasonably foreseeable purpose, [and] (2) the unreasonably dangerous condition existed when the [product] left the defendant's hands." *Ball v. Takeda Pharms. Am., Inc.*, 963 F. Supp. 2d 497, 505 (E.D. Va. 2013) (citing *Chestnut v. Ford Motor Co.*, 445 F.2d 967, 968-69 (4th Cir. 1971); *Logan v. Montgomery Ward & Co.*, 219 S.E.2d 685, 687 (Va. 1975)); *see also Sutherlin v. Lowes Home Ctrs.*, 2014 WL 7345893, at *26 (E.D. Va. Dec. 23, 2014) (reciting the same elements). Importantly, "a manufacturer does not insure its product's

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[1] A federal district court sitting in diversity applies the substantive law of the forum state, including its choice-of-law rules. *Klaxon Co. v. Stentor Mfg. Co.*, 313 U.S. 487, 496 (1941). For that reason, the Court applies Virginia's choice-of-law rules. Under Virginia's choice of law rules, the substantive law of the place of the wrong (*lex loci delicti*) would apply to Plaintiff's claims. *Quillen v. Int'l Playtex, Inc.*, 789 F.2d 1041, 1044 (4th Cir. 1986). In cases sounding in tort and involving the implantation of a defective medical device, the place of original implantation generally represents the place of the wrong. *See General Assur. of Am., Inc. v. Overby-Sewell*, 533 F. App'x 200, 206 (4th Cir. 2013) (stating that the place of the wrong is where "the last event necessary to make an [actor] liable for an alleged tort takes place."); *Porter v. DePuy Orthopaedics*, 2019 WL 3979656, at *5 (E.D. Va. Aug. 6, 2019) (applying substantive law of state where plaintiff underwent knee replacement surgery rather than law of state where he received treatment for complications from this surgery); *see also Sharp v. Ethicon, Inc.*, 2020 WL 1434566, at *2 (W.D. Ark. Mar. 24, 2020) (applying substantive law of state of implantation under the *lex loci delicti* doctrine); *Wise v. C.R. Bard, Inc.*, 2015 WL 502010, at *3 (S.D. W.Va. Feb. 5, 2015) (applying substantive law of place where plaintiff's original surgery took place, and not that of where she was treated for her injuries). Plaintiff here fails to allege where her original surgery took place. However, both parties urge the application of Virginia law, so the Court will do so as well for the purposes of deciding this Motion.

safety, and need not 'supply an accident-proof product.'" *Ball*, 963 F. Supp. at 505. "A product may be 'unreasonably dangerous' in three ways, 'if it is defective in assembly or manufacture, unreasonably dangerous in design, or unaccompanied by adequate warnings concerning its hazardous properties.'" *Sykes v. Bayer Pharms. Corp.*, 548 F. Supp. 2d 208, 215 (E.D. Va. 2008) (quoting *Morgen Indus., Inc. v. Vaughan*, 471 S.E.2d 489, 492 (Va. 1996)). Thus, Virginia products liability law recognizes three negligence-based causes of action: (1) negligent manufacture, (2) negligent design and (3) negligent failure to warn. *Austin v. Clark Equip. Co.*, 821 F. Supp. 1130, 1133 (W.D. Va. 1993) (citing *Bly v. Otis Elevator Co.*, 713 F.2d 1040, 1043 (4th Cir. 1983)).

In its Motion to Dismiss, Defendant argues that Plaintiff's Amended Complaint fails to allege facts sufficient to support a claim for each of these causes of action. (Def.'s Mem. at 4.) The Court agrees that Plaintiff's claims under Counts One and Two fail, because Plaintiff fails to plead facts sufficient to allege a defect in the SNF, but Plaintiff's claims under Count Three survive because of this Court's recognition of a post-sale duty to warn.

A. Negligent Manufacture

A manufacturing defect exists when a product fails to conform to its intended design. *Sykes*, 548 F. Supp. 2d at 215 (citing Restatement (Third) of Torts: Product Liability § 2(a) (1997)). Thus, to succeed on a claim of negligent manufacture, the plaintiff must allege that the defendant did not make the product as it intended. *Id.* Indeed, even at the pleadings stage, "[a] bare allegation of a 'defect' is no more than a legal conclusion." *Ball*, 963 F. Supp. 2d at 505. This district has affirmed that "the nature of the defect must be demonstrated to prove an actionable claim . . . at the pleading stage." *Fields v. Jobar Int'l*, 2014 WL 1513289, at *10

(E.D. Va. Apr. 16, 2014). Plaintiffs must allege facts indicating how a product "may have been manufactured improperly." *Id.*

Plaintiff does not allege facts specifying a plausible defect in the SNF's manufacture. Plaintiff merely states that "fracturing of an IVC filter, like the SNF, is caused by structural failure or defect," without actually identifying the defect. (Am. Compl. ¶ 12.) As asserted, these facts merely show the possibility that the fracturing resulted from a defect in the SNF device without alleging an actual defect in either its design or manufacture. *See Porter*, 2019 WL 3979656, at * 8 (finding that plaintiff had failed to allege a connection between the loosening of the connecting pieces in a knee implant and a defect in the manufacture of the implant) (report and recommendation adopted by the District Court in *Porter v. DePuy Orthopaedics, Inc.*, 2019 WL 3978407 (E.D. Va. Aug. 22, 2019)). In fact, from the facts pled, it appears just as likely that another explanation, including conditions of the human body or external forces, caused the fracturing, making Plaintiff's claims that her injuries resulted from a manufacturing defect merely conceivable as opposed to plausible.

In *Ball*, the Court dismissed an analogous claim of negligent manufacture at the motion to dismiss stage, because the plaintiff had failed to allege facts that would permit the Court to conclude that a manufacturing defect existed. *Ball*, 963 F. Supp. 2d at 505. The plaintiff claimed that a drug used to treat acid reflux and gastrointestinal ailments produced and distributed by the defendant caused her fallopian tubes to close and for her to develop Stevens-Johnson Syndrome. *Id.* The plaintiff offered numerous studies and research demonstrating impaired fertility in other women following the use of drugs similar to the one produced by the defendant. *Id.* at 500. However, despite clear evidence that the drug had detrimental effects on consumers, the court dismissed her claims, stating that the plaintiff failed to "articulate how [the

drug] may have been manufactured improperly." *Id.* at 505. As in *Ball*, Plaintiff fails to articulate what went wrong in the manufacturing process and connect that to the detrimental effects caused by the device.

Also, the Court fails to see how Plaintiff's continued reliance on bare allegations of "lack of testing," both in her complaint and in her response brief, establish the existence of a manufacturing defect. (Am. Compl. ¶¶ 46-47; Pl.'s Resp. at 6.) Virginia does not recognize "failure to test" as a theory of liability separate and apart from the traditional products liability claims discussed above. *Ball*, 963 F. Supp. 2d at 506; *see also Powell v. Diehl Woodworking Mach., Inc.*, 198 F. Supp. 3d 628, 633-34 (E.D. Va. 2016) (noting that because "failure to test" fails as an independently viable products liability claim, "the Court must either fit this claim into one of the traditional theories or dismiss it altogether"). Rather, "a manufacturer's duty to test its products 'is subsumed within the general duty of the manufacturer to avoid acting in a negligent manner.'" *Sardis v. Overhead Door Corp.*, 446 F. Supp. 3d 47, 54 (E.D. Va. 2020) (quoting *Powell*, 198 F. Supp. 3d at 633).

Thus, while a manufacturer's failure to test its products alone cannot give rise to liability under a negligent manufacturing claim, an allegation that a manufacturer deviated from its standard manufacturing process by failing to test the particular product at issue may establish a sufficient basis for such a claim. *Id.* at 55; *see also Sykes*, 548 F. Supp. 2d at 215 n. 5 (noting that issues in the testing process "might be regarded as a species of manufacturing-defect claim," as the Restatement's description of the manufacturing process includes, "the making of such inspections and tests during the course of manufacture and after the article is completed as the manufacturer should recognize as reasonably necessary to secure the production of a safe article") (internal quotations omitted). For example, in *Sykes*, the plaintiffs brought a products

liability action against the manufacturer of HypRho-D, a drug that had allegedly harmed their unborn son when his pregnant mother was injected with it. *Id.* at 212. The plaintiffs alleged that the manufacturer had "failed to conduct testing on HypRho-D to determine whether the mercury in thimerosal, in the quantity contained in a recommended dose of the HypRho-D was dangerous." *Id.* at 215. Construing these allegations as a negligent manufacturing claim, the court rejected it, because the plaintiffs had merely alleged that the manufacturer had failed to test the drug "generally." *Id.* To succeed, the plaintiffs needed to allege that the manufacturer had failed to test the particular dose that harmed their son, because a manufacturing defect claim depends on evidence that the product departs from its intended design. *Id.* As such, a comprehensive failure to test does not give rise to the conclusion that the manufacturer did not make the allegedly defective product as it intended. *Id.*

Plaintiff's allegations of inadequate testing fail to support a defective manufacturing claim for similar reasons. Plaintiff makes general allegations that "Defendant did not conduct adequate or proper testing." (Am. Compl. ¶¶ 45-46.) However, nowhere does she state or even suggest that this failure to test represents a deviation from Defendant's normal manufacturing process. As such, the Court cannot conclude that the product used by Plaintiff did not conform to its intended design. Consequently, the Amended Complaint has provided no basis to believe that a manufacturing defect exists.

For these reasons, the Court dismisses without prejudice Count One of Plaintiff's Amended Complaint.

B. Negligent Design

For analogous reasons, Plaintiff's Amended Complaint fails to state a plausible claim for negligent design. Defendant argues that Plaintiff fails to allege any design issues, or "plead any

facts that would permit the Court to conclude that such design issues existed." (Def.'s Mem. at 6.) The Court agrees.

An unreasonable design defect exists when "the foreseeable risks of harm posed by the product could have been reduced or avoided by the adoption of a reasonable alternative design." Restatement (Third) of Torts: Products Liability § 2(b) (1997); *see also Torkie-Tork v. Wyeth*, 739 F. Supp. 895, 899 (E.D. Va. 2010) ("To prevail on a negligent design defect under Virginia law, 'the plaintiff must prove that the product contained a defect which [sic] rendered it unreasonably dangerous for ordinary or foreseeable use.'") (quoting *Alevromagiros v. Hechinger Co.*, 993 F.2d 417, 420 (4th Cir. 1993)). To state a claim of negligent design, Plaintiff must contend that Defendant could have designed the product differently before putting it into the stream of commerce, "or that such a design is even feasible." *Ball*, 963 F. Supp. 2d at 505. At minimum, Plaintiff must provide some allegation that a design defect existed and that such a defect proximately caused Plaintiff's injuries. *Id.*

As in Count I, Plaintiff again appears to rely on claims that "Defendant did not conduct adequate and proper testing of the SNF" to support her claim that a design defect existed. (Am. Compl. ¶¶ 51-53.) As previously articulated, allegations of "failure to test" must fit into an already recognized theory of liability, because, standing alone, they cannot support an independent cause of action. However, in the context of design defects, allegations of "failure to test" go to the unreasonableness of the defect, rather than the existence of the defect itself. *See Powell*, 198 F. Supp. 3d at 634 (finding that plaintiff's allegations that defendant "failed to properly test" the product, failed as a negligent design claim, because plaintiff "[did] not allege that the failure to test led to a defective design, or that additional testing would have led to a 'reasonable alternative design'"); *see also Ball*, 963 F. Supp. 2d at 504 (finding plaintiff's

contentions that defendant failed to "adequately warn about the product's adverse effects, properly instruct consumers regarding [the product's] use, and adequately test the product 'before placing it in use' insufficient to state a design defect claim).

Indeed, Plaintiff's Amended Complaint contains no other suggestion that the design of the SNF caused the fracturing of the device or that an alternative design could have prevented the fracturing of the device. By failing to allege a connection between the fracturing of the device "and a defect in the design or manufacture of the [product], [the complaint] render[s] a defect in the manufacture or design of the implant merely conceivable, not plausible." *Porter*, 2019 WL 3979656, at *8. Moreover, "it is impossible for this Court to determine whether or not Plaintiff states a plausible claim for negligent design without some disclosure in the pleading of the alleged defect or deficiency in the design of the product, and how such defect was the proximate cause of Plaintiff's alleged injuries." *Id.*

Plaintiff does attempt to raise a proposed alternative design in her response to Defendant's Motion to Dismiss, stating "an 'all in one' piece where the pieces are not bonded as in the SNF, may have been a better design which would not have caused a fracture . . . Perhaps, if each of the leg/struts had been designed differently where the foot/base tapered in a ball design, then there would have been no puncturing." (Pl.'s Resp. at 7.) While such suggestions identify alternative designs that may meet the pleadings standard, they come too late. These suggestions do not appear in Plaintiff's Amended Complaint, a deficiency that proves fatal to this claim. *See Davis v. Cole*, 999 F. Supp. 809, 813 (E.D. Va. 1998) (refusing to consider additional allegations in response to motion to dismiss).

For these reasons, the Court dismisses without prejudice Count II of Plaintiff's Amended Complaint.

C. Failure to Warn

Plaintiff also asserts a failure to warn claim, detailed in Count Three of the Amended Complaint. Defendant argues in its Motion to Dismiss that Plaintiff fails to allege that Defendant knew of any of the alleged issues with the SNF before or at the date of implantation, and that no post-sale duty to warn exists under Virginia law. (Def.'s Mem. at 8-9.) Defendant further asserts that, because Virginia recognizes the learned intermediary doctrine, Plaintiff must plausibly allege "that the doctor [who implanted the SNF] was not warned, something Plaintiff has not done in her Amended Complaint." (Def.'s Mem. at 9.) Defendant argues that Plaintiff merely makes "equivocal" assertions as to whether or not Defendant warned her doctor, and that these equivocal assertions do not meet the requisite pleading standard. (Def.'s Mem. at 8.)

Generally, to prevail on a failure to warn claim, Plaintiff must establish that Defendant "(1) knew or had reason to know that the [product] was or was likely to be dangerous for its intended use, (2) had no reason to believe that those for whose use the [product] was supplied would realize its dangerous condition, and (3) failed to exercise reasonable care to inform them of its dangerous condition or of the facts which made it likely to be dangerous." *Sutherlin*, 2014 WL 7345893, at *26 (E.D. Va. Dec. 23, 2014) (citing *Featherall v. Firestone Tire & Rubber Co.*, 252 S.E.2d 358, 366 (Va. 1979)); *Funkhouser v. Ford Motor Co.*, 736 S.E.2d 309, 313 (Va. 2013). A manufacturer must "give a reasonable warning, not the best possible one." *Pfizer, Inc. v. Jones*, 272 S.E.2d 43, 45 (Va. 1980). A warning that alerts a party of the very injury that the plaintiff seeks to recover for generally meets this standard. *Ball*, 963 F. Supp. 2d at 504.

As alleged, the issues with the SNF did not arise until, at the earliest, the 2010's, whereas the implantation of the device in Plaintiff occurred "in the early 2000's." (Am. Compl. ¶¶ 13-15, 21, 28.) Plaintiff alleges no facts indicating that Defendant "knew or had reason to know" of the

dangers of the device at the time of her procedure. Thus, none of the facts alleged by Plaintiff support a plausible right to relief under a time-of-sale failure to warn.

However, while a duty to warn clearly exists at the time of sale of a product, the Virginia Supreme Court has yet to recognize a post-sale duty to warn. As a result, the district courts in Virginia have developed two lines of thought regarding this cause of action, with some courts stating that a manufacturer has a post-sale duty to warn if it appeared reasonable to provide such warnings upon discovering the dangers of the product, and others holding manufacturers liable only if they knew or should have known of the dangers at the time of the sale. *Compare Rash v. Stryker Corp.*, 589 F. Supp. 2d 733, 735 (W.D. Va. 2008) (finding that "the Supreme Court of Virginia would allow a cause of action based on a negligent breach of a post-sale duty to warn"); *and McAlpin v. Leeds & Northrup Co.*, 912 F. Supp. 207, 210-12 (W.D. Va. 1996) (reasoning that no Virginia caselaw supports the idea "that a manufacturer should be relieved of liability for failure to warn . . . if it learns of a potential danger to a buyer only after the product has left the manufacturer's hands"); *with Estate of Kimmel v. Clark Equip. Co.*, 773 F. Supp. 828, 831 (W.D. Va. 1991) ("No duty to warn arises simply because a manufacturer discovers new information about a product after the product has already left its hands."); *and Ambrose v. Southworth Prods. Corp.*, 953 F. Supp. 728, 733 (W.D. Va. 1997) (adopting the same conclusion as *Kimmel*).

These cases diverge largely due to their interpretation of a portion of Fourth Circuit dicta that distinguishes between the duty to warn under a theory of implied warranty and the duty to warn under a theory of negligence. *Bly v. Otis Elevator Co.*, 713 F.2d 1040 (4th Cir. 1983). In *Bly*, the Fourth Circuit emphasized that a negligence theory of liability focuses on the conduct of the manufacturer, whereas a warranty theory of liability focuses on the condition of the product itself. *Id.* at 1045. As a result, "under a negligence theory, the duty to warn is continuous and is

not interrupted by manufacture or sale of the product . . . whereas the duty to warn under a theory of [implied warranty] exists only at the time the product leaves the manufacturer's control." *Id.* at 1045-46. In *McAlpin*, the court interpreted this distinction to mean that a court may consider not just what the manufacturer knew at the time of sale, but rather, what they learned post-sale in assessing whether a manufacturer violated his duty to warn. *McAlpin*, 912 F. Supp. at 209. The court believed that the use of the word "continuous," "does not support the argument that th[e] court must look only to the information available to the manufacturer when the product left its hands if the theory under which the plaintiff has sued is negligence. To the contrary, this language indicates that such a focus should be utilized only if the governing theory is implied warranty." *Id.* at 210. Conversely, the *Kimmel* court acknowledged that *Bly* implied a "continuous" duty to warn, but concluded that "[al]though the duty to warn is continuous from the date of manufacture/sale, it requires the manufacturer to warn only about dangerous conditions it knew about, or in the exercise of reasonable care should have known about, at that time." *Kimmel*, 773 F. Supp. at 831. No duty to warn exists for dangerous conditions "that became reasonably recognizable or apparent only at some later period of time," as requiring otherwise would "create a duty that otherwise did not exist under Virginia law." *Id.*

This district has adopted the *McAlpin* view of the post-sale duty to warn, noting that the Fourth Circuit seems to have reiterated its support for this view in a later case. *Powell*, 198 F. Supp. 3d at 635 (citing *Island Creek Coal Co. v. Lake Shore, Inc.*, 832 F.2d 274, 280 (4th Cir. 1987) ("There seems no question that, if the defendant discovered that the machine it had sold to the plaintiffs was not safe, it had a duty to notify the plaintiffs and a failure to do so would be actionable negligence.")). This opinion also recognizes several legal and policy-based reasons articulated by the Virginia Supreme Court that support this view of the duty. *Powell*, 198 F.

Supp. 3d at 635 (citing *Featherall*, 252 S.E.2d at 366 (adopting § 388 of the Second Restatement of Torts, which places no limits on negligence actions where a manufacturer knew or should have known about that danger); *Ford Motor Co. v. Phelps*, 389 S.E.2d 454, 456-57 (Va. 1990) (making no distinction between pre- and post-sale evidence when discussing the admission of evidence of defects occurring both before and after the sale of products); *General Motors Corp. v. Lupica*, 379 S.E.2d 311, 314 (Va. 1989) (explaining that imposing a post-sale duty to warn respects the court's preference that the manufacturer should bear this burden because it has superior knowledge of the product as compared to the consumer)).

Based on this Court's reading of the Fourth Circuit dicta and the reasons articulated in *Powell*, this Court adopts the *McAlpin* view of the post-sale duty to warn, finding that "a manufacturer [is] liable for failing to warn about dangers discovered after selling a product, if it was reasonable for the manufacturer to provide such warnings upon discovering the dangers." *Powell*, 198 F. Supp. 3d at 364-65 (citing *McAlpin*, 912 F. Supp. at 209-20).

Therefore, while none of the facts alleged by Plaintiff support a plausible right to relief under a time-of-sale failure to warn, the facts do support a plausible claim for post-sale failure to warn. Applying the post-sale duty to warn as articulated above, and taking the allegations in the Amended Complaint as true, a reasonable trier of fact might find based on the 2013 study regarding the complications caused by IVC filters, the 2016 study regarding the high fracture rates of the SNF, the 2016 study regarding the high perforation rates of the SNF, the warnings issued by the FDA and the "numerous complaints regarding injuries," that it would have been reasonable for Defendants to provide warnings after the sale and implantation of the device. (Am. Compl. ¶¶ 13-16, 18, 20.)

In its Motion to Dismiss, Defendant posits that, regardless of whether a post-sale duty to warn exists, the Learned Intermediary Doctrine bars this claim, because Plaintiff has not plausibly stated that Defendants did not warn Plaintiff's physician of the dangers of the SNF. (Def.'s Mem. at 8.) Specifically, Defendant says that Plaintiff's "equivocal" phrasing in the Amended Complaint makes her allegations merely speculative rather than plausible. (Def.'s Mem. at 8.) Plaintiff responds that Virginia has not yet adopted the Learned Intermediary Doctrine, so the Court should not even apply this doctrine. (Pl.'s Resp. at 10.)

As with the post-sale duty to warn, Virginia has not formally adopted the Learned Intermediary Doctrine, but this district, the Fourth Circuit and Virginia courts have consistently applied it or its principles in products liability cases. *See, e.g., Talley v. Danek Med., Inc.*, 179 F. 3d 154, 164-64 (4th Cir. 1999) (applying the doctrine to affirm dismissal of medical products liability action); *Pfizer, Inc. v. Jones*, 272 S.E.2d 43, 44 (Va. 1980) ("We start with elementary principles of law . . . '[I]n the case of prescription drugs, it is the general rule that the duty of the drug manufacturer is to warn the physician who prescribes the drug in question.'") (citing 2 R. Hursh & H. Bailey, American Law of Products Liability § 8:11, 173 (2d ed.1974)); *Hamlett v. Virginia Vascular Assocs.*, 2003 WL 22382792, at *4 (Va. Cir. Ct. 2003) (noting that the Supreme Court of Virginia "applied the [learned intermediary] doctrine to a manufacturer of prescription drugs") (citing *Pfizer*, 272 S.E.2d at 44). Given this extensive application of the Learned Intermediary Doctrine, this Court finds it appropriate to apply it in this case.

"Under the Learned Intermediary Doctrine, manufacturers of prescription medical products have a duty only to warn physicians, rather than patients, of the risks associated with the use of the product." *Talley v. Danek Medical, Inc.*, 7 F. Supp. 2d 725, 731 (E.D. Va. 1998). These products include "medical devices that can be prescribed or installed only by a physician."

Talley, 179 F.3d at 163. Defendant argues that Plaintiff's allegations that Defendant "failed to warn 'consumers, medical providers ***and/or*** government authorities' about the alleged injuries caused by the SNF" is "equivocal at best, and speculative at worst." (Def.'s Mem. at 8 (emphasis in original).) Defendant states that "such equivocal allegations suggest that Plaintiff is unsure as to whether [Defendant] warned her medical providers," and that this equivocality should cause her claim to fail. (Def.'s Mem. at 8.)

The Court disagrees with this assertion. The pleading standard for a motion to dismiss requires factual allegations that raise Plaintiff's right to relief above a speculative level. While Plaintiff's language in the above quoted passage of the Amended Complaint does suggest some level of speculation and uncertainty, other portions of the Amended Complaint bolster her claim. Plaintiff avers that "Defendant owed a duty and breached that duty by not informing medical providers and federal authorities about the problems associated with the SNF," and that "the doctor who implanted the device was not aware of all the potential and actual risks and complications with respect the SNF." (Am. Compl. ¶¶ 25, 30.) Read together, these allegations, taken as true, nudge Plaintiff's allegations from merely conceivable to plausible.

D. Failure to Allege Specific Date of Implantation

As a final point in its Motion to Dismiss, Defendant argues that Plaintiff's failure to specify the date or year of implantation of the SNF negates all of her claims, as Defendant "did not acquire the rights in and liabilities attributable to the SNF until October 19, 2001." (Def.'s Mem. at 9.) Defendant avers that Plaintiff's implantation must have occurred after this date or none of her claims can survive. (Def.'s Mem. at 9.)

In general, "a corporation that purchases the assets of another corporation is not liable for the debts and contingent liabilities of the selling corporation." *Taylor v. Atlas Safety Equip. Co.,*

Inc., 808 F. Supp. 1246, 1251 (E.D. Va. 1992). This rule encompasses product liability claims. *Id.* However, Virginia recognizes four exceptions to this rule:

> In order to hold a purchasing corporation liable for the obligations [including contingent product liability claims] of the selling corporation, it must appear that (1) the purchasing corporation expressly or impliedly agreed to assume such liabilities; (2) the circumstances surrounding the transaction warrant a finding that there was a consolidation or *de facto* merger of the two corporations; (3) the purchasing corporation is merely a continuation of the selling corporation; or (4) the transaction is fraudulent in fact.

Id. (quoting *Harris v. T.I., Inc.*, 413 S.E.2d 605, 609 (Va. 1992)).

At this point in the litigation, the Court must assume the truth of Plaintiff's claims that Defendant "manufactured, produced, designed, sold, distributed, and/or marketed" the SNF at the time that she was injured by the device. (Am. Compl. ¶ 5.) While Defendant's assertion that it did not acquire "the rights in and liabilities attributable to the SNF" until 2001 might ultimately prove true and provide Defendants with a defense later in the litigation, the Court cannot consider evidence pertaining to this assertion at this time. *See Davis*, 999 F. Supp. at 813 ("The court may not consider additional allegations when ruling on a motion to dismiss and must consider the facts as asserted in the complaint . . . to be true."). As such, the Court cannot determine whether Defendant assumed the liabilities attributable to the SNF through one of the exceptions enumerated above. Therefore, at this time, Defendant's assertions prove too indefinite and unsubstantiated to defeat Plaintiff's claims.

IV. CONCLUSION

For the reasons set forth above, the Court GRANTS IN PART and DENIES IN PART Defendant's Motion to Dismiss (ECF No. 16). Specifically, Court DISMISSES WITHOUT PREJUDICE Counts One and Two of Plaintiff's Amended Complaint (ECF No. 9), but DENIES Defendant's Motion as to Count Three.

An appropriate order will issue.

Let the Clerk file a copy of this Memorandum Opinion electronically and notify all counsel of record.

/s/
David J. Novak
United States District Judge

Richmond, Virginia
Date: December 23, 2020